General Assembly **Substitute Bill No. 371**

February Session, 2016 *SB00371PH 041316 *

AN ACT CONCERNING THE USE OF EXPERIMENTAL DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2016*) (a) For purposes of this section:

(1) "Investigational drug, biological product or device" means a drug, biological product or biological device that has successfully completed a phase one clinical trial of the federal Food and Drug Administration but has not yet been approved for general use by the federal Food and Drug Administration and remains under investigation in a clinical trial approved by the federal Food and Drug Administration;

(2) "Patient" means a person who has a terminal illness, verified by the person's treating physician, who is not being treated as an inpatient in a hospital licensed under chapter 368v of the general statutes;

(3) "Treating physician" means a physician licensed under chapter 370 of the general statutes who has primary responsibility for the medical care of the patient and treatment of the patient's terminal illness; and

(4) "Terminal illness" means a medical condition that a patient's treating physician anticipates, with reasonable medical judgment, will result in the patient's death or a state of permanent unconsciousness

from which recovery is unlikely within a period of one year.

(b) A patient is eligible to receive treatment with an investigational drug, biological product or device if the patient has (1) considered all other treatment options currently approved by the federal Food and Drug Administration, (2) been unable to participate in a clinical trial for the terminal illness that is not more than one hundred miles from the patient's home address, or not been accepted to a clinical trial not more than one week after completion of the clinical trial application process, (3) received a recommendation from his or her treating physician for an investigational drug, biological product or device, (4) given written, informed consent, as provided in subsection (c) of this section, for the use of the investigational drug, biological product or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent of the minor or a legal guardian of the minor or adult patient has given such written, informed consent on the patient's behalf, and (5) obtained written documentation from his or her treating physician stating that the patient meets the requirements of this subsection.

(c) A patient gives written informed consent when the patient, or if the patient is a minor or lacks the mental capacity to provide informed consent, a parent of the minor or the legal guardian of the minor or adult patient, signs a written document, verified by the patient's treating physician and a witness that, at a minimum: (1) Explains the currently approved and conventionally recognized products and treatments for the terminal illness from which the patient suffers; (2) confirms the patient's concurrence with his or her treating physician in believing that all currently approved and conventionally recognized products and treatments are unlikely to prolong the patient's life; (3) clearly identifies the specific proposed investigational drug, biological product or device with which the patient is seeking to be treated; (4) describes the potentially best and worst outcomes of using the investigational drug, biological product or device with a realistic description of the most likely outcome, including the possibility that

new, unanticipated, different or worse symptoms might result and that death could be hastened by the proposed treatment, based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition; (5) states clearly that the patient's health carrier, as defined in section 3 of this act, treating physician or other health care provider is not obligated to pay for any care or treatments resulting from the use of the investigational drug, biological product or device; (6) states clearly that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with an investigational drug, biological product or device but that hospice care may be reinstated if such treatment ends and the patient meets hospice eligibility requirements; (7) states clearly that in-home health care may be denied if such treatment begins; and (8) states that the patient understands that the patient is liable for the costs of, or associated with, the investigational drug, biological product or device and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product or device states otherwise.

(d) Notwithstanding the provisions of chapter 370 of the general statutes, the Department of Public Health or the Connecticut Medical Examining Board shall not revoke, fail to renew, suspend or take any disciplinary action against a physician based solely on the treating physician's recommendation to a patient regarding access to, or treatment with, an investigational drug, biological product or device, provided such recommendation is consistent with medical standards of care.

(e) No official, employee or agent of the state shall prevent, or attempt to prevent, a patient who is eligible under subsection (b) of this section from accessing an investigational drug, biological product or device.

(f) Nothing in this section shall create a cause of action against the patient's treating physician or any other person or entity involved in

the care of a patient being treated with an investigational drug, biological product or device for any harm done to such patient resulting from the investigational drug, biological product or device.

Sec. 2. (NEW) (*Effective October 1, 2016*) (a) A manufacturer of an investigational drug, biological product or device, as defined in section 1 of this act, may make available the manufacturer's investigational drug, biological product or device to a patient who is eligible under subsection (b) of section 1 of this act and may (1) provide the investigational drug, biological product or device to such patient without receiving compensation, or (2) require such patient to pay the costs of, or associated with, the manufacture of the investigational drug, biological product or device.

(b) Nothing in this section shall create a cause of action against a manufacturer of an investigational drug, biological product or device that makes available such investigational drug, biological product or device to an eligible patient for any harm done to such patient resulting from the investigational drug, biological product or device.

Sec. 3. (NEW) (*Effective October 1, 2016*) (a) As used in this section, "health carrier" means an insurance company, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues a health insurance policy providing coverage of the type provided in subdivisions (1), (2), (4), (11), (12) and (16) of section 38a-469 of the general statutes in this state.

(b) A health carrier may provide coverage for an investigational drug, biological product or device, as defined in section 1 of this act, that is made available pursuant to section 2 of this act to an insured patient who is eligible under subsection (b) of section 1 of this act.

(c) A health carrier may deny coverage to an insured patient from the time such patient begins treatment with the investigational drug, biological product or device for a period not to exceed six months from

the date such patient ceases treatment with the investigational drug, biological product or device, except that coverage may not be denied for a preexisting condition or for coverage for benefits that commenced prior to the date such patient begins such treatment.

(d) Nothing in this section shall affect the provisions of sections 38a-504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the general statutes concerning insurance coverage for certain costs associated with clinical trials. Treatment with an investigational drug, biological product or device is not considered a clinical trial for the purposes of said sections.

(e) Nothing in this section shall create a cause of action against a health carrier that provides coverage for an investigational drug, biological product or device pursuant to subsection (b) of this section, or denies coverage in accordance with subsection (c) of this section, to an insured patient who begins treatment with an investigational drug, biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2016*	New section
Sec. 2	*October 1, 2016*	New section
Sec. 3	*October 1, 2016*	New section

INS *Joint Favorable Subst. -LCO*

PH *Joint Favorable*